Remarks and Arguments

Applicants thank the Examiner for the courtesies extended during the October 5, 2005 telephonic interview.

Claims 1, 2, 4-34, 36-39, 45-51 and 53-68 are pending. The pending claims stand rejected. Each of the rejections is addressed below.

Claims 1, 21, 36, 45, 53, 55, 57, 66, 67, and 68 have been amended. Support for the amendments to claims 1, 45, and 66 can be found, for example, in Figs. 6a-14b. Support for the amendment to claims 21 and 53 can be found in e.g., Fig. 6a and 16a. Support for the amendment to claims 36, 55, 57, 67, and 68 is found in paragraph 42 of the specification as filed. It is believed that no new matter has been added.

Claim 15, has been cancelled.

35 U.S.C. § 102

Claim 1, 2, 5, 6, 12-15, 18-21, 24, 26-29, 31, 34, 36, 38, 45-51, and 53-68 are rejected 35 U.S.C. § 102 as being unpatentable over U.S. Patent No. 6,776, 791 issued to Stallings et al. Claims 1, 2, 5, 6, 12-15, 18, 36, 38, 45, 46, 62, and 66 are further rejected pursuant to 35 U.S.C. § 102 as being unpatentable over U.S. Patent No. 6,077,297 issued to Robinson et al.

The standard for anticipation under 35 U.S.C. § 102 requires that each and every element as set forth in the claim be found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The Office has not met this standard with respect to any of the pending claim rejections.

In determining what the prior art teaches, it is generally not acceptable to rely on the dimensions in the drawings. In particular, MPEP 2125 states in relevant part:

> **PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE**

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.").

Explanation of certain features of the invention

A summary of certain features of the invention are provided in paragraphs 55 and 56 of the application as filed. These state:

> A concern with existing delivery systems for self-expanding stents is control of stent delivery. For example, due to their elastic characteristics, self-expanding stents have a tendency to propel themselves axially outwardly from their restraining sheaths before the sheaths have been completely retracted. When this occurs, control of stent placement is compromised since the stent may overshoot the desired deployment site. Further, once the stent has been completely deployed, subsequent adjustment of the stent deployment location can be difficult because re-sheathing typically cannot be readily accomplished.
>
> To address the above concerns, the delivery system 10 is preferably equipped with an interlock configuration that constrains relative axial movement between the stent 12 and the inner tube 14 until after the sheath 16 has been fully retracted. For example, when the stent 12 is mounted on the inner tube 14 and restrained in the compressed orientation by the sheath 16 as shown in FIG. 2A, a first interlock geometry (e.g., male interlock structures 82 as shown in FIG. 2A) located at the proximal end of the stent 12 interlocks with a second interlock geometry (e.g., female interlock structures 84 as shown in FIG. 2A) defined by the proximal marker 27 (also referred to as a collar). The interlock geometries remain interlocked to constrain axial movement of the stent 12 until after the sheath has been retracted beyond a predetermined location (e.g., the proximal-most end 12a of the stent 12). When the sheath 12 has been retracted beyond the predetermined location, the interlock geometry of the stent 12 is allowed to expand. As the interlock geometry of the stent expands, the interlock geometry of the stent disengages from the interlock geometry of the marker 27 thereby allowing the inner tube 14 of the catheter to be moved axially relative to the stent without interference from the interlock geometries.

U.S. Patent No. 6,776,791

Claims 1, 2, 5, 6, 12-15, 18-21, 23, 26-29, 31, 34, 36, 38, 45-51, 53-68 stand rejected in light of Stallings et al.

The Patent Office rejected the pending claims on the basis that "the diameter of the [Stallings] stent is about 20mm, therefore, at least a portion of each first and second interlock structures being positioned a distance at most 5mm from the cell defining region". During the telephonic interview, the Patent Office indicated that the above conclusion was based on the measured distances in the drawings. Applicants respectfully submit that it is improper to rely on the drawings to determine the distance of the interlock structures from the cell defining region because Stallings et al. do not teach that the drawings are to scale (see MPEP Section 2125, quoted above). Stallings et al. in fact does not teach interlock structures positioned at most 5mm from the cell defining region.

In addition, the Office states "[r]egarding claim 18, the elongated member can be interpreted as element structure 50". Applicants respectfully disagree. Claim 18 includes the limitation "wherein the elongated member extends completely through the implant". Stallings et al. describes element structure 50 as a tip. See, e.g., col. 3, line 23, and Fig. 1. The dictionary at http://www.yourdictionary.com defines a tip as "[t]he end of a pointed or projecting object". Since a tip refers to the end of an object rather than an element that extends completely through the object, Applicants respectfully disagree with this characterization.

For at least these reasons, Applicants respectfully request that the Patent Office withdraw this rejection and allow all claims.

U.S. Patent No. 6,077,297

Claims 1, 2, 5, 6, 12-15, 18, 36, 38, 45, 62 and 66 stand rejected under 35 U.S.C. §102 in light of Robinson et al. The Patent Office states alleges that Robinson et al. disclose at least a portion of each first and second interlock structures positioned at a distance at most of 5 mm from the cell defining region. Applicants respectfully disagree for the same reasons as stated above in reference to Stallings et al.

Applicants do note that Robinson et al. disclose the use of hooks on a stent to secure it to a graft (see e.g., col. 7 last paragraph), and dimensions are provided for such hooks. However, such a stent/graft arrangement does not anticipate the current claims. The interlock disclosed by Applicants is used for the purposes described above as quoted in paragraphs 55-56. They prevent premature axial movement of the implant during implantation, and they are releasably disconnected upon withdrawal of the sheath from the interlocks. These interlocks are not used for the purpose of attaching a stent to a graft.

Independent claim 1 as modified requires that at least a portion of each of the first and second interlock structures are outside the cell defining region. These first and second interlock structures interlock to constrain axial movement of the implant relative to the elongated member (i.e., catheter). At least a portion of the first and second interlock structures are at most 5 mm from the cell defining region. These characteristics are not taught or suggested by Robinson et al.

These difference are more than simply a design choice. The dimensions taught by Robinson et al. for hooks for attaching a stent to a graft are irrelevant since they serve a different function than the interlocks in the claim.

Robinson et al. do disclose interlocks but these are within the cell defining portion of the implant (see e.g., Figures 4 and 16b). Positioning at least a portion of the first and second interlock structures outside the cell defining region means that these structures will not axially deform when the implant begins to expand. Thus, they provide protection from premature disengagement that might otherwise be caused by the sheath being partially removed from the implant and the implant partially expanding therebecause. The implant is held securely in place until the sheath is substantially or totally withdrawn from the interlock, thus preventing axial movement of the implant during the retraction of the sheath.

Independent claim 21 discloses an implant delivery system having an implant with enlargements at most 5mm from the cell defining region and the catheter elongated element having interlock structures. The enlargements must be at the terminal ends of the struts and outside the cell defining region. The prior art does not teach this combination for reasons analogous to those stated in regard to claim 1.

Independent claim 29 further requires an implant having at least two female interlock structures positioned at most 5mm from the cell defining structure and the catheter elongated member including male interlock members that interlock with the female interlock members to constrain radial expansion of the implant. The claim further requires that the female interlock members not expand when the stent is expanded. This claim again is different from Robinson et al., and the differences are more than simple design choices. The female interlock element of Applicants' invention does not change shape upon expansion and hence provides a more secure fit for the reasons listed in reference to claim 1, above.

It is respectfully submitted that modified claims 38, 45, 53, and 66 each disclose interlocks are/ or enlargements that interlock to constrain axial movement of the implant. They further include the requirement that one or ore of the enlargements or interlocks (or at least a part thereof) be at most 5mm from the cell defining region. Thus, these claims are believed to be novel and non-obvious for reasons analogous to those stated for claim 1.

Modified claims 36, 55, 57, 67, and 68 are further believed to be novel and non-obvious. Robinson et al. discloses the use of a marker on the catheter (see col. 9, third full paragraph). However, there is no teaching to apply it to the second interlock structure. This is again more than just a simple design choice. A radiopaque marker on the second interlock structure will allow the user to ascertain the exact location of the implant in the patient's body. This functionality cannot be obtained by simply applying a marker to the elongated tube of the catheter since the tube is longer than the implant. In other words, determining the position of the tube in the body is not the same as determining the exact position of the implant in the body. Since it is the implant that needs to be implanted in the correct position (while the tube is removed), it is particularly advantageous to know the exact position of the implant during the implantation procedure.

It is respectfully submitted that independent claim 62 is novel and non-obvious over Robinson et al. for reasons analogous to those listed in reference to claim 1. Robinson et al. do not teach a male and female interlock that constrain axial movement of the implant with at least a portion of the female interlock

structure being positioned a distance from the cell defining region of the implant, the distance being at most 5 millimeters from the cell defining region.

35 U.S.C. § 103

Claims 4, 22, and 30 as well as 16, 17, 24, 25, 32, 33, 37 and 39 all stand rejected as being allegedly obvious in light of Stallings et al. Each of these rejections is addressed below.

The Prima Facie Case Requirement

The Patent and Trademark Office (PTO) bears the burden of initially establishing a prima facie case of obviousness. MPEP § 2142. MPEP § 2143 provides the standard required to establish a prima facie case of obviousness. "First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one or ordinary skill in the art, to modify the reference or to combine what the reference teaches. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references combined) must teach or suggest all the claim limitations."

The motivation to make the claimed invention and the reasonable expectation of success must both be found in the prior art, not the applicant's disclosure. *In re Vaeck,* 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). The references must be considered as a whole and must suggest the desirability, and thus the obviousness of making the combination. *Hodosh v. Block Drug Col, Inc.,* 229 U.S.P.Q. 182, 187 n.5 (Fed. Cir. 1986); MPEP § 2141.

Claim 4, 22, and 30

Claim 4, 22, and 30 are all dependent claims. Applicants respectfully submit that these claims are novel and non-obvious for the same reasons as the claims from which they depend.

Each of these claims requires a radiopaque marker positioned adjacent a particular location. The Office alleges that Stallings discloses the invention as

substantially claimed, but admits that Stallings does not disclose a radiopaque marker. Applicants respectfully request that the Patent Office explain its basis for finding that claims 4, 22, and 30 would be obvious over Stallings et al. which does not set out all the elements of the rejected claims. If the Office is relying on personal information to support its position that the difference between Stallings et al. and the claimed invention would be a mere obvious design choice Applicants request that the Examiner submit an affidavit in compliance with 37 CFR § 1.104(d)(2).

Applicants respectfully submit that the Patent Office has not met the burden of the prima facie case and respectfully request that the rejection be withdrawn.

Claims 16, 17, 24, 25, 32, 33, 37 and 39

The Patent Office further alleges claims 16, 17, 24, 25, 32, 33, 37 and 39 are obvious and therefore unpatentable in light of Stallings et al. The Office alleges that Stallings et al. disclose the invention as substantially claimed, but admits that Stallings et al. does not disclose a portion having a distance at most 1 millimeter from the cell defining region of the implant. The Office alleges that at the time the invention was made, it would have been an obvious design choice for the skilled artisan to modify the length of the interlock structures such that the length was at most 1mm because the Applicant has not disclosed the 1mm distance provides an advantage or solves a problem. The Office goes on to allege that the skilled artisan would have expected Applicant's invention would perform equally well with the above 5 mm distance. Applicants respectfully disagree.

The Office seems to suggest that because Stallings et al. allegedly disclose a 5mm distance that 1 mm distance would be a mere obvious design choice. The argument presented by the Office, however, fails because it is based upon the erroneous premise that Stallings et al. disclose at least a portion of each first and second interlock structures positioned at a distance at most of 5 mm from the cell defining region. Applicants' reasons for disagreeing with this premise is explained in reference to the 35 USC 102 rejection over Stallings et al., above.

In addition, the features of the claimed invention are not a matter of simple design choice. Rather, such features are useful since a shorter distance between the

cell defining region and the interlock structure(s) means that the entire implant will have a smaller length. This means that a smaller length of lumen will be impacted by the implanted device thus possibly leading to less complications in the patient. Applicants respectfully request withdrawal of the rejection.

Response to additional Office comments

The Office states "[t]he phrase 'at least a portion of the first interlock structure' in independent claims 1, 36, and 38 makes the claims broad". However, Applicants note that these claims do not appear to be formally rejected or objected for this reason. Even had they been rejected, Applicants would respectfully disagree. MPEP 2173.04 states that "[b]readth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear... then the claims comply with 35 U.S.C. 112, second paragraph." A skilled artisan would be able to understand the requirement that at least a portion of each of the first and second interlock structures be within the required distance from the cell defining region of the implant. Therefore, to the extent that the Office is making a rejection, Applicants respectfully disagree and request reconsideration.

Additional art

US 6,863,685 (Davilla et al.) disclose a stent delivery apparatus having a stop. The stop makes frictional contact with the inner surface of the sheath and helps to push the stent out of the sheath during deployment (col. 13, lines 18-24). Davilla et al. fails to teach interlocks that prevent the stent from moving axially in both directions while the sheath is being retracted and the stent is expanding (see col 14, first paragraph). Applicants invention however has interlocks (see e.g., claim 1) which prevent axial movement in either direction while the sheath is being retracted. Thus, Applicants claim different structures with different functions than Davilla, and it is respectfully submitted that Applicants' claims are novel and non-obvious for these reasons.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account.

Respectfully submitted

_____ Date: 10/13/05

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